

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------|-----------------------|
| Applicant's or agent's file reference Y0424-PCT | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/JP2004/010781 | International filing date (<i>day/month/year</i>) 22.07.2004 | Priority date (<i>day/month/year</i>) 24.07.2003 | |
| International Patent Classification (IPC) or national classification and IPC C07D215/56, A61K31/47, C07D401/12, A61K31/4709, C07D405/12, C07D401/06, | | | |
| Applicant ASTELLAS PHARMA INC. | | | |

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| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4. This report contains indications relating to the following items:</p> <table> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </tbody> </table> | <input checked="" type="checkbox"/> | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. II | Priority | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VI | Certain documents cited | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application | | | | | | | | | | | | | | | | | | | | | | |

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|-----------------------------------------|-----------------------------------|
| Date of submission of the demand | Date of completion of this report |
| Name and mailing address of the IPEA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010781

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- international search (Rule 12.3 and 23.1(b))
- publication of the international application (Rule 12.4)
- international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished
 the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

- the description, pages _____
- the claims, nos. _____
- the drawings, sheets/figs _____
- the sequence listing (*specify*): _____
- any table(s) related to sequence listing (*specify*): _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages _____
- the claims, nos. _____
- the drawings, sheets/figs _____
- the sequence listing (*specify*): _____
- any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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| International application No. | PCT/JP2004/010781 |
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| Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|

1. Statement

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-21</u> | YES |
| | Claims _____ | NO |
| Inventive step (IS) | Claims <u>1-21</u> | YES |
| | Claims _____ | NO |
| Industrial applicability (IA) | Claims <u>1-21</u> | YES |
| | Claims _____ | NO |

2. Citations and explanations (Rule 70.7)

Document 1: GB 2372986 A (XENOVA LTD.), 11 September 2002 (11.09.02), entire text; claim 12
(Family: none)

Document 2: WO 02/98856 A2 (SCHERING AG.), 12 December 2002 (12.12.02), entire text & US 2003/60474 A & EP 1412349 A2 & AU 2002/316191 B

Document 3: JP 2001-139555 A (Pfizer Products Inc.), 22 May 2001 (22.05.01), entire text & EP 1099701 A1 & CA 2325358 A1 & US 2002/132806 A

Document 4: WO 01/57037 A1 (COR THERAPEUTICS INC.), 09 August 2001 (09.08.01), entire text; Registry No.478004-95-4, 478004-97-6 & AU 2001/36644 B & US 2002/25961 A & US 2002/77486 A & EP 1257550 A1 & JP 2003-522177 A & US 2003/162774 A & US 2004/147576 A

Document 5: DATABASE CHEMCATS ON STN, (2003) Accession No. 2003:2205826, Registry No.375351-23-8

Document 6: DATABASE CHEMCATS ON STN, (2002) Accession No. 2002:2172297, Registry No.375351-23-8

Document 7: DATABASE CHEMCATS ON STN, (2002) Accession

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010781

| Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | No. 2002:163154, Registry No.375351-23-8 |
| Document 8: | WO 98/23592 A1 (WAKUNAGA PHARM CO., LTD.), 04 June 1998 (04.06.98), entire text & EP 945435 A1 & US 6136823 A |
| Document 9: | WO 02/92571 A1 (ASTRAZENECA AB.), 21 November 2002 (21.11.02), entire text & EP 1387830 A1 & AU 2002/306038 B |
| Document 10: | JP 50-29574 A (ALLEN & HANBURY LTD.), 25 March 1975 (25.03.75), entire text & DE 2407744 A1 & FR 2218896 A1 & GB 1433774 A & CA 1025856 A1 |
| Document 11: | JP 50-35191 A (ALLEN & HANBURY LTD.), 03 April 1975 (03.04.75), entire text & DE 2415767 A1 & FR 2230356 A1 & US 3943141 A & GB 1444369 A & US 4024255 A & CA 1029726 A1 |
| Document 12: | JP 2002-531567 A (ASTRAZENECA UK LTD.), 15 June 2002 (15.06.02), entire text & WO 00/34283 A1 & EP 1135391 A1 & US 2003/144305 A & EP 1386917 A1 & EP 1386921 A1 |
| Document 13: | WO 03/22214 A2 (Millennium Pharm Inc.), 20 March 2003, entire text & US 2003/153556 A & AU 2002/336462 B |
| <p>The quinolone derivative as presented in formula (I-a) set forth in claim 7 and the platelet aggregation inhibitor or P2Y12 inhibitor containing the quinolone derivative presented by the formula set forth in claim 1 are not disclosed in any of documents 1-13 listed above and cited in the international search report. Moreover, these features would not be obvious to a person skilled</p> | |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

in the art.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010781

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

IPC

C07D401/14, C07D417/12, C07413/12, C07D409/12,
A61K31/4725, C07D401/04, C07D405/06, C07D405/04,
C07F9/60, /00, A61P7/02, A61P9/10, A61P41/00